AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q97391

Application No.: 10/594,127

**AMENDMENTS TO THE CLAIMS** 

This listing of claims will replace all prior versions and listings of claims in the

application:

LISTING OF CLAIMS:

1. (currently amended): A process for producing a composition of solifenacin or a salt

thereof for use in a solid formulation, the composition containing the crystal of solifenacin or a

salt thereof, wherein the amorphous content is within a range showing no influence on product

stability which comprises at least one step selected from the group consisting of (i) a step of wet-

granulation using a solvent to solifenacin or a salt thereof, wherein the amount of solifenacin or a

salt thereof to be dissolved per 1 mL of the solvent is less than 0.1 mg, (ii) a step of reducing the

amount or the addition rate of a solvent, when the solvent makes solifenacin or a salt thereof into

an amorphous state, wherein the amount of solifenacin or a salt thereof to be dissolved per 1 mL

of the solvent is 10 mg or more, and (iii) a step of promoting the crystallization of a composition

obtained by wet-granulation.

2. (currently amended): A The process for producing a composition of solifenacin or a

salt thereof for use in a solid formulation according to claim 1, wherein the amorphous content is

77 % or less.

3. (currently amended): A The process for producing a composition for use in a solid

formulation according to claim 1 or 2, which is produced by a manufacturing process including a

step of blending solifenacin or a salt thereof with an excipient without using any solvent,

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followed by comprises compressing compression molding into a granulated composition for use

in a solid formulation.

4. (currently amended): A The process for producing a composition for use in a solid

formulation according to claim 1 or 2, which is produced by a manufacturing process including a

step of adding a solvent to solifenacin or a salt thereof, wherein the amount of solifenacin or a

salt thereof to be dissolved per 1 mL of the solvent is less than 0.1 mg, and wherein the solvent is

acetone, hexane, or a mixture thereof.

5. (canceled).

6. (currently amended): A The process for producing a composition for use in a solid

formulation according to claim 1 or 2, which is produced by a manufacturing process including a

step of adding a solvent to prepare solifenacin or a salt thereof into an amorphous state, wherein

the amount of solifenacin or a salt thereof to be dissolved per 1 mL of the solvent is 10 mg or

more, and wherein the solvent is water, methanol, ethanol, or a mixture thereof.

7.-9. (canceled).

10. (currently amended): A pharmaceutical composition of solifenacin or a salt thereof

for use in a solid formulation, the composition containing crystalline and amorphous solifenacin

or a crystalline and amorphous salt thereof, together with an inhibitor of an amorphous

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preparation, wherein the inhibitor of an amorphous preparation is a substance having an ethylene oxide chain.

11. (canceled).

12. (currently amended): A pharmaceutical composition according to claim 1117,

wherein the substance having an ethylene oxide chain is polyethylene glycol.

13. (new): The process for producing a composition for use in a solid formulation

according to claim 1, wherein the step of reducing the amount or the addition rate of a solvent is

to adjust the moisture content of the granules in a binder solution to a given value.

14. (new): The process for producing a composition for use in a solid formulation

according to claim 13, wherein the moisture content of the granules is 9% or less.

15. (new): The process for producing a composition for use in a solid formulation

according to claim 1, wherein the step (iii) of promoting the crystallization is at least one

selected from the group consisting of heating and/or moisturizing process, microwave irradiation

process, low-frequency irradiation process, ultrasonic irradiation process, and thermoelectron

irradiation process.

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16. (new): The process for producing a composition for use in a solid formulation according to claim 15, wherein the heating and/or moisturizing process is performed under conditions of 25°C and 75 RH.

17. (new): The pharmaceutical composition according to claim 10, wherein the substance having an ethylene oxide chain is polyethylene glycol, polyethylene oxide, polyoxyethylene polyoxypropylene block copolymer, polyoxyethylene hardened castor oil, or polyethylene glycol fatty acid ester.